



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0662]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Applications for Food and Drug Administration Approval to Market a New Drug -- Patent Submission and Listing Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0513. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Applications for Food and Drug Administration Approval to Market a New Drug: Patent
Submission and Listing Requirements

OMB Control Number 0910-0513--Extension

Section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(c)(1)) requires all NDA applicants to file, as part of the NDA, the patent number and the expiration date of any patent that claims the drug for which the applicant submitted the application or that claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. Section 505(c)(2) of the FD&C Act imposes a similar patent submission obligation on holders of approved NDAs when the NDA holder could not have submitted the patent information with its application. After approval of an NDA, under section 505(b)(1) of the FD&C Act, FDA publishes the patent information in the list entitled “Approved Drug Products with Therapeutic Equivalence Evaluations” (the Orange Book). When the patent information is submitted after NDA approval, section 505(c)(2) of the FD&C Act directs FDA to publish the patent information upon its submission.

FDA regulations in §§ 314.50(h) (21 CFR 314.50(h)) and 314.53 (21 CFR 314.53) clarify the types of patent information that must and must not be submitted to FDA as part of an NDA, an amendment, or a supplement to an NDA, and also require persons submitting an NDA, an amendment, or a supplement to make a detailed patent declaration on Form FDA 3542a, or when submitting information on a patent after approval of the NDA or supplement, to make a detailed patent declaration using Form FDA 3542.

The reporting burden for submitting an NDA, an amendment, or a supplement to an NDA, in accordance with § 314.50(a) through (f), (i), (h), and (k) has been estimated by FDA and the collection of information has been approved by OMB under control number 0910-0001. In addition, the reporting burden for submitting an appropriate patent certification or statement for each patent listed in the Orange Book for one drug product approved in an NDA that is pharmaceutically equivalent to the proposed drug product for which the original 505(b)(2) application was submitted (if certain criteria are met) in accordance with § 314.50(i)(1)(i)(C) and the reporting burden for submitting an amended patent certification in certain circumstances in accordance with § 314.50(i)(6) are approved by OMB under OMB control number 0910-0786. In addition, the reporting burden for responding to a patent listing dispute in accordance with § 314.53(f)(1) and the reporting burden for submitting corrections, changes, or withdrawal of patent information in accordance with § 314.53(f)(2) also are approved by OMB under OMB control number 0910-0786. We are not re-estimating these approved burdens in this document. Only the reporting burdens associated with patent submission and listing, as described below, are estimated in this document.

The information collection reporting requirements are as follows:

Section 314.50(h) requires that an NDA, or an amendment or a supplement to an NDA, contain patent information described under § 314.53. Section 314.53 requires that an applicant submitting an NDA, or an amendment or a supplement to an NDA, except as provided in § 314.53(d)(2), submit on Forms FDA 3542 and 3542a the required patent information described in this section. Section 314.53(d)(2) requires submission of patent information only for a supplement that seeks approval to add or change the dosage form or route of administration, to add or change the strength, to change the drug product from prescription to over-the-counter use,

or to revise previously submitted patent information that differently or no longer claims the product as changed by the supplement.

Compliance with the information collection burdens under §§ 314.50(h) and 314.53 consists of submitting with an NDA, or an amendment or a supplement to an NDA (collectively referred to as an “application”) the required patent declaration(s) on Form FDA 3542a for each patent that claims the drug or a method of using the drug that is the subject of the new drug application or amendment or supplement to it and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product (§ 314.53(b)). Such patents claim the drug substance (active ingredient), drug product (formulation and composition), or method(s) of use. If a patent is issued after the application is filed with FDA, but before the application is approved, the applicant must submit the required patent information on Form FDA 3542a as an amendment to the application, within 30 days of the date of issuance of the patent.

Within 30 days after the date of approval of an application, the applicant must submit Form FDA 3542 for each patent that claims the drug substance (active ingredient), drug product (formulation and composition), or approved method(s) of use of the product for listing in the Orange Book. For patents issued after the date of approval of an application, Form FDA 3542 must be submitted within 30 days of the date of issuance of the patent. In addition, an NDA applicant’s amendment to the description of the approved method(s) of use claimed by the patent must be submitted within the timeframes described in §§ 314.50(i)(4) and 314.94(a)(12)(vi) (21 CFR 314.94(a)(12)(vi)) to be considered timely filed.

Description of Respondents: The respondents to this collection of information are NDA applicants for original applications, amendments, or supplements to an NDA or NDA applicants submitting information on a patent after approval of the NDA or supplement.

The final rule “Abbreviated New Drug Applications and 505(b)(2) Applications,” implemented portions of Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) and also amended certain regulations regarding 505(b)(2) applications and abbreviated new drug applications (ANDAs) to facilitate compliance with and efficient enforcement of the FD&C Act (81 FR 69580; October 6, 2016) (MMA Final Rule). In the MMA Final Rule, we estimated that the burden for Form FDA 3542a would be reduced by 5 hours from 20 hours to 15 hours per response; we further estimated that the burden for Form FDA 3542 would increase by 5 hours from 5 to 10 hours per response. The burden hours were adjusted to shift a portion of the time spent preparing Form FDA 3542a to the estimated time spent preparing Form FDA 3542 to reflect the additional time spent by the NDA holder to develop the use code in accordance with FDA’s revised regulations and identify the specific section(s) and subsection(s) of labeling that describe the specific approved method of use claimed by the patent. The burden hours of Forms FDA 3542 and 3542a in this notice reflect the reporting burden approved by OMB under OMB control number 0910-0786 in connection with the MMA Final Rule. The effective date of the MMA Final Rule was December 5, 2016. Consequently, the annual reporting burden estimated below is based on calendar year 2017 data only to reflect the post-MMA Final Rule regulatory requirements and reporting burden estimate.

In the *Federal Register* of May 20, 2019 (84 FR 22858), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimate the burden of the information collection as follows:

Table 1.--Estimated Annual Reporting Burden

| 21 CFR 314.50 (citing § 314.53) | No. of Respondents | No. of Responses per Respondent | Total Annual Responses CY 2017 | Hours per Response | Total Hours |
|------------------------------------|-----------------------|---------------------------------------|-----------------------------------|-----------------------|----------------|
| Form FDA 3542 | 281 | 2.875 | 808 | 10 | 8,080 |
| Form FDA 3542a | 310 | 2.084 | 646 | 15 | 9,690 |
| Total | | | 17,770 | | |

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

For purposes of this analysis, we consider the number of respondents to correspond to the number of NDAs and efficacy supplements submitted or approved, respectively, in calendar year (CY) 2017, even though one company may submit or hold multiple NDAs or may submit multiple efficacy supplements to one or more NDAs. FDA approved 127 NDAs and 154 efficacy supplements to NDAs during CY 2017, which corresponds to 281 respondents. Based on information provided by the Orange Book staff, approximately 623 patent records were created in CY 2017, which corresponds to an estimated 513 Forms FDA 3542 submitted to FDA for listing of patent information in the Orange Book for NDAs approved in CY 2017 and an estimated 110 Forms FDA 3542 submitted to FDA for listing of patent information in the Orange Book for efficacy supplements approved in CY 2017. In addition, based on information provided by the Orange Book staff and FDA's experience, we estimate that approximately 185 Forms FDA 3542 were submitted in CY 2017 to modify patent information, which results in an estimated total of 808 Forms FDA 3542 submitted in CY 2017.

During calendar year 2017, FDA received 141 original NDAs and 169 efficacy supplements to NDAs for FDA review and approval. We estimate that applicants submitted approximately 405 Forms FDA 3542a for the original NDAs submitted during CY 2017. In addition, based on a review of the submitted efficacy supplements, FDA received 241 Forms

FDA 3542a with the efficacy supplements received during CY 2017, resulting in a total of 646 Forms FDA 3542a submitted in CY 2017.

Our estimated burden for the information collection reflects an overall decrease. We attribute this adjustment to a decrease in the number of duplicative submissions of Forms FDA 3542a and 3542 in connection with supplements submitted or approved after the effective date of the MMA final rule, and improved data collection from upgraded data software tools.

Dated: August 29, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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